

## **REMARKS**

### **Status of claims and amendments**

Claims 1-44 are pending in the application. In the Office Action dated August 3, 2007, the Examiner rejected claims 1-3, 5-7, 9, 17, 18, 20, 24, 25, and 27-30 under 35 U.S.C. 102(b) as being anticipated by Wilk; rejected claims 22-23 under 35 U.S.C. 102(b) as being anticipated by McPherson et al; rejected claims 34-35, 37, and 39-44 under 35 U.S.C. 102(e) as being anticipated by Kuehn et al; rejected claims 4, 10-13, 21, and 31-33 under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of McGarry et al; rejected claims 8, 26, 36, and 38 under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of McPherson et al; rejected claim 14 under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of Kuehn et al; rejected claims 15-16 under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of Kammerer et al; and rejected claim 19 under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of Yoon. These rejections are respectfully traversed in light of the instant amendments.

In this amendment, claims 1, 5, and 24 were amended to further define the claimed invention over the cited prior art. Specifically, these claims were amended to recite that the second tissue engaging device comprises opposed articulable arms with a tissue piercing element disposed at a distal end of at least one said arm, said articulable arms each configured for releasably engaging the interior of the hollow organ, with said second tissue engaging device being moveable relative to the first tissue engaging device (claims 1 and 5), or that the plurality of members include a first member having a first securing part configured to engage a first stomach tissue section and a second member having a second securing part configured to engage a second stomach tissue section, said means comprising an actuating mechanism operatively linking the first and second members to facilitate simultaneous dependent movement of said members to draw together the first and second stomach tissue sections (claim 24).

For support for these amendments, please see at least Figures 25-27 and pp 36-37, in which an exemplary second tissue engaging device comprises opposed articulable arms, *e.g.* stapler arms 230 (Figures 25-26; see also p. 36 lines 14-19 and 26-29), with a tissue piercing element, *e.g.* tissue engagement device 300 (Figure 27; see also p. 37, lines 12-13) disposed at a distal end of at least one said arm, as recited in claims 1 and 5. The plurality of members, *e.g.* stapler arms 230, include a first member 230 having a first securing part, *e.g.* graspers 250 or tissue engagement device 300, configured to engage a first stomach tissue section, and a second member 230 having a second securing part, *e.g.* graspers 250 or tissue engagement device 300, configured to engage a second stomach tissue section, said means comprising an actuating mechanism, *e.g.* stapler yoke 240 and/or joint 242, operatively linking the first and second members 230 to facilitate simultaneous dependent movement of said members to draw together the first and second stomach tissue sections (Figures 25-27 and p 36, lines 17-20, 26-29), as recited in claim 24.

Claims 22-23 are canceled.

Claims 25-29 are amended for further clarity, and to correct typographical errors.

New claims 45-52 are presented to further define the claimed invention over the cited prior art. For support for these amendments, please see at least Figures 25-27 and pp 36-37.

No new matter is added.

#### **Wilk: Claims 1 and 5**

Independent claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk. Applicant respectfully asserts that claims 1 and 5, as amended, are patentable over Wilk because, among other things, Wilk does not disclose or suggest “a second tissue engaging device...comprising opposed articulable arms with a tissue piercing element disposed at a distal end of at least one said arm,... with said second tissue engaging device being moveable relative to the first tissue engaging device,” as recited in both claims 1 and 5.

The Examiner has relied on Wilk's Figure 7 and column 9, line 44 to column 10, line 55 as allegedly disclosing a first tissue engaging device 36 and a second tissue engaging device 35. However, the three "tissue engaging devices" 34-36 illustrated in Figure 7 and described in the cited passage operate independently of one another. No two of these "devices" can be said to constitute opposed articulable arms making up a single tissue engaging device, let alone a single tissue engaging device that itself is moveable relative to another tissue engaging device, as required by the claims.

Further, assuming *arguendo* that instrument 34 or 36 includes two "arms," *i.e.* the hinged jaw or scissor components shown, neither of these instruments includes a tissue piercing element, as required by the claims.

Wilk simply does not disclose or suggest "a second tissue engaging device...comprising opposed articulable arms with a tissue piercing element disposed at a distal end of at least one said arm,... with said second tissue engaging device being moveable relative to the first tissue engaging device," as recited in claims 1 and 5. Claims 1 and 5, as well as their dependents, claims 2-4, 6-21, and 45-52, are thus patentable over Wilk. Withdrawal of this rejection is respectfully requested.

#### **Wilk: Claim 24**

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilk. Applicant respectfully asserts that claim 24, as amended, is patentable over Wilk because, among other things, Wilk does not disclose or suggest "an actuating mechanism operatively linking the first and second members to facilitate simultaneous dependent movement of said members to draw together the first and second stomach tissue sections" as recited in claim 24.

By similar reasoning as that above, no two instruments 34-36 can be construed as being operatively linked with simultaneous dependent movement; in fact, Wilk specifically states that each instrument 34-36 includes a separate actuator 34c-36c (column 9, lines 47-50).

Further, assuming *arguendo* that instrument 34 or 36 includes first and second members *i.e.* the hinged jaw or scissor components shown, neither of these instruments draws together first and second tissue sections, but only clamps or cuts a single tissue section. Claim 24 requires “a first member having a first securing part configured to engage a first stomach tissue section and a second member having a second securing part configured to engage a second stomach tissue section, [and] an actuating mechanism operatively linking the first and second members to facilitate simultaneous dependent movement of said members to draw together the first and second stomach tissue sections,” which is not anticipated by a single clamp or pair of scissors. Claim 24, as well as its dependents, claims 25-33, is thus patentable over Wilk. Withdrawal of this rejection is respectfully requested.

**Wilk: New Claim 45**

In addition to depending from allowable claim 1, claim 45 is further patentable over Wilk, because, among other things, Wilk does not disclose or suggest “a second tissue engaging device ...comprising opposed articulable arms,” as required by base claim 1, and “a second actuating mechanism cooperating with the second tissue engaging device and operatively linking the articulable arms to facilitate simultaneous dependent movement of said arms,” as required by claim 45, by similar reasoning as that above, under heading “claim 24.” Claim 45, as well as its dependents, claims 46-48, is thus further patentable over Wilk. Withdrawal of this rejection is respectfully requested.

**Kuehn: Claim 34**

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Kuehn et al. This rejection is respectfully traversed because, among other things, Kuehn et al. does not disclose or suggest “an elongated member configured for transoral placement in the stomach,” as required by claim 34.

The Examiner has referred to Kuehn's cardiac catheter 126 as allegedly corresponding to the inventive elongated member. However, Kuehn's apparatus is intended to be deployed into the heart through an incision in the chest:

One approach to introduce the instruments into the heart involves the direct introduction of a passageway through the wall of the heart....Alternatively, the instruments can be introduced into the heart by a vascular approach. In these approaches, a catheter is introduced into an artery or vein and directed into the heart....Suitable gripping and fastening instruments have appropriate dimensions to fit through the cardiac catheter into the heart (Column 5, lines 29-31 and 42-50).

Applicant asserts that any instrument with these "appropriate dimensions" would not be long enough for transoral placement in the stomach. Even in the instance in which the catheter is introduced into an artery or vein and directed into the heart, surely the distance through which the catheter is placed in the vein would be minimized for the health and comfort of the patient. In fact, Kuehn's disclosure goes on to state that "[g]enerally, tubular section 108 [of cardiac catheter 126] has a length from about 4 cm to about 15 cm" (column 6, lines 32-33), which is not long enough for transoral placement in the stomach.

Kuehn et al. does not disclose or suggest "an elongated member configured for transoral placement in the stomach," as required by claim 34. Claim 34, as well as its dependents, claims 35-44, is thus patentable over Kuehn. Withdrawal of this rejection is respectfully requested.

#### **Kuehn: Claim 35**

In addition to depending from allowable claim 34, claim 35 is further patentable over Kuehn, because, among other things, Kuehn does not disclose or suggest "the first movable member includes a first securing part configured to engage a first tissue section and the second movable member includes a second securing part configured to engage a second tissue section," as required by claim 35.

The Examiner referred to Kuehn's fastener applicator 404 as allegedly corresponding to the inventive first and second movable members, and to tack 424 and cap 426 as allegedly corresponding to the inventive securing parts. However, "[t]ack 424 engages cap 426" (column 9, lines 49-50) at a *single* tissue section.

Kuehn does not disclose or suggest "the first movable member includes a first securing part configured to engage a first tissue section and the second movable member includes a second securing part configured to engage a second tissue section," as required by claim 35. Claim 35 is thus further patentable over Kuehn. Withdrawal of this rejection is respectfully requested.

### **Conclusions**

In view of the foregoing, it is believed that all claims now pending in this Application are in condition for allowance. Should the Examiner have any continuing objections, the Applicant respectfully asks the Examiner to contact the undersigned at 415-442-1109 (direct line) in order to expedite allowance of the case.

Authorization is granted to charge any outstanding fees due at this time for the continued prosecution of this matter to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310 (matter no. 064391-5001-US03).

Respectfully submitted,

Date: February 4, 2008

By: 

Jessica C. Stahnke, Reg. No. 57,570, for  
Thomas D. Kohler, Reg. No. 32,797  
MORGAN, LEWIS & BOCKIUS LLP  
2 Palo Alto Square  
3000 El Camino Real, Suite 700  
Palo Alto, CA 94306  
(415) 442-1106